Item 1: Establishment of the Maximum Residue Limits for Agricultural and Veterinary Chemicals in Foods

The Food Sanitation Act authorizes the Ministry of Health, Labour and Welfare (MHLW) to establish residue standards (maximum residue limits, "MRLs") for pesticides, feed additives, and veterinary drugs (hereafter referred to as "agricultural and veterinary chemicals") that may remain in foods. Any food for which standards are established pursuant to the provisions in Article 13, Paragraph 1 of the act is not permitted to be marketed in Japan unless it complies with the established standards

On May 29, 2006, Japan introduced the Positive List System[1] for agricultural and veterinary chemicals in food. All foods distributed in the Japanese marketplace are subject to regulation of the system.

(1) The MHLW is going to modify or newly set MRLs in some commodities for the following substances:

Pesticides : Cyflumetofen, Tiadinil, Thiencarbazone-methyl
Veterinary drugs : Dichloroisocyanuric acid

(2) Designation of Substances Used as Ingredients of Agricultural Chemicals and Other Chemical Substances That Are Stipulated to be "Not Detected" in Food

Veterinary drugs : Gentian violet

<The manner of submitting comments>
The Ministry of Health, Labour and Welfare (MHLW) will amend the existing standards and specifications for food as shown in this document. Please provide comments in writing by Friday January 15, 2021. After the given date, comments should be directed to the enquiry point in accordance with the WTO/SPS Agreement.

If you wish to request Japan to adopt the same limits as your country's MRLs, you are requested to submit data supporting your country's MRLs, such as risk assessment and residue data.

<Contact person>
Food Safety Standards and Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916

Mr. MIURA Tomoaki (miura-tomoaki@mhlw.go.jp)
Tel : 03-5253-1111 (ex 4290) Fax: 03-3595-2432

[1] The aim of the positive list system is to prohibit the distribution of any foods which contain agricultural chemicals at amounts exceeding a certain level (0.01 ppm) in the Japanese marketplace unless specific maximum residue limits (MRLs) have been set.

Summary

(1) Establishment of Maximum Residue Limits for Agricultural Chemicals in Food

Cyflumetofen (pesticides: Acaricide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the Ministry of Agriculture, Forestry and Fisheries (MAFF) with the intention to expand its use pattern. This action will not strengthen the current regulation for any commodities.

Tiadinil (pesticides: Fungicide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting them by the MAFF.

Thiencarbazone-methyl (pesticides: Herbicide): Not permitted for use in Japan. The MHLW is going to establish an MRL in a certain commodity in response to a request for setting it by the MAFF with the intention to newly register this substance as a pesticide. This action will not strengthen the current regulation for any commodities.

Dichloroisocyanuric acid (veterinary drugs: Disinfectant): Permitted for use in Japan. The MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System. This action will not strengthen the current regulation for any commodities.

(2) Designation of Substances Used as Ingredients of Agricultural Chemicals and Other Chemical Substances that are stipulated to be "Not Detected" in Foods

Gentian violet (veterinary drugs: Parasiticide): Not permitted for use in Japan. The MHLW has decided to implement the risk management for Gentian violet designated as a substance used as an ingredient of agricultural chemicals and other chemical substances that is stipulated to be "Not detected" in foods.
Synonym: Crystal violet, Methylrosanilinium chloride
Residue definition: Gentian violet and Leuco gentian violet

Dichloroisocyanuric acid

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cattle, muscle	0.8	0.8	§		
Pig, muscle	0.8	0.8	§		
Other terrestrial mammals, muscle	0.8	0.8	§		
Cattle, fat	0.8	0.8	§		
Pig, fat	0.8	0.8	§		
Other terrestrial mammals, fat	0.8	0.8	§		
Cattle, liver	0.8	0.8	§		
Pig, liver	0.8	0.8	§		
Other terrestrial mammals, liver	0.8	0.8	§		
Cattle, kidney	0.8	0.8	§		
Pig, kidney	0.8	0.8	§		
Other terrestrial mammals, kidney	0.8	0.8	§		
Cattle, edible offal	0.8	0.8	§		
Pig, edible offal	0.8	0.8	§		
Other terrestrial mammals, edible offal	0.8	0.8	§		
Milk	0.8	0.8	§		
Chicken, muscle	0.8	0.8	§		
Chicken, fat	○ 2	0.8	§		
Chicken, liver	0.8	0.8	§		
Chicken, kidney	0.8	0.8	§		
Chicken, edible offal	2	2	§		
Chicken eggs	0.8	0.8	§		

The residue definition for Dichloroisocyanuric acid is Isocyanuric acid.

* The uniform limit 0.01 ppm will be applied to commodities not listed above.

* Shaded figures indicate provisional MRLs.

* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

○：Commodities for which MRLs are to be raised.

§：Permitted for use in Japan.

Cyflumetofen

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Sweet potato	0.01		Request		
Japanese yam (including Chinese yam)	0.2	0.2	§		
Sugar beet	0.01		Request		
Other composite vegetables	25	25	§		
Asparagus	5	5	§		
Mitsuba	60	60	§		
Tomato	0.4	0.4		0.3	0.4 USA
Pimiento (sweet pepper)	5	5	§		
Egg plant	2	2	§		
Cucumber (including gherkin)	1	1	§		
Water melon		0.2	§		
Water melon (whole commodity after removal of stems)	0.4		§		
Melons		0.2	§		
Melons (whole commodity after removal of stems)	0.9		§		
Other cucurbitaceous vegetables	0.5	0.5	§		
Kidney beans, immature (with pods)	○ 7		Request		
Other vegetables	○ 90	70	§ ・ Request		
Unshu orange, pulp		0.2	§		
Unshu orange (whole commodity)	5		§	0.3	
Citrus natsudaidai, whole	5	5	§	0.3	
Lemon	10	10	§	0.3	
Orange (including navel orange)	10	10	§	0.3	
Grapefruit	10	10	§	0.3	
Lime	10	10	§	0.3	
Other citrus fruits	10	10	§	0.3	
Apple	2	2	§	0.4	
Japanese pear	2	2	§	0.4	
Pear	2	2	§	0.4	
Quince	0.4	0.4		0.4	
Loquat	0.3	0.3	§		
Peach		0.2	§		
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems)	10		§		
Nectarine	2	2	§		
Apricot	10	10	§		
Japanese plum (including prune)	1	1	§		
Mume plum	10	10	§		
Cherry	10	10	§		
Strawberry	2	2	§	0.6	
Grape	3	3	§	0.6	
Japanese persimmon	2	2	§	0.4	
Other fruits	2	2	§	0.01	
Ginkgo nut	0.01	0.01		0.01	
Chestnut	0.01	0.01		0.01	
Pecan	0.01	0.01		0.01	
Almond	0.01	0.01		0.01	
Walnut	0.01	0.01		0.01	
Other nuts	0.01	0.01		0.01	
Tea	40	40	§		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Hop	○ 10		Request		
Other spices	20	20	§	0.3	
Other herbs	○ 90	0.05	§・Request		
Cattle, muscle	0.01	0.01		0.01	
Pig, muscle	0.01	0.01		0.01	
Other terrestrial mammals, muscle	0.01	0.01		0.01	
Cattle, fat	0.01	0.01		0.01	
Pig, fat	0.01	0.01		0.01	
Other terrestrial mammals, fat	0.01	0.01		0.01	
Cattle, liver	0.02	0.02		0.02	
Pig, liver	0.02	0.02		0.02	
Other terrestrial mammals, liver	0.02	0.02		0.02	
Cattle, kidney	0.02	0.02		0.02	
Pig, kidney	0.02	0.02		0.02	
Other terrestrial mammals, kidney	0.02	0.02		0.02	
Cattle, edible offal	0.02	0.02		0.02	
Pig, edible offal	0.02	0.02		0.02	
Other terrestrial mammals, edible offal	0.02	0.02		0.02	
Milk	0.01	0.01		0.01	

The residue definition for agricultural products is cyflumetofen only. The definition for animal products is sum of cyflumetofen and metabolite B-1【α,α,α-Trifluoro-*o*-toluic Acid】, expressed as cyflumetofen.

* The uniform limit 0.01 ppm will be applied to commodities not listed above.

* Diagonal line means a food category to which MRL applies is not set.

* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

○: Commodities for which MRLs are to be raised.

§: Permitted for use in Japan.

Request: Request for setting/revising MRL was made by the MAFF.

Tiadinil

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	● 0.9	1	§		
Cattle, muscle	0.01		Request		
Pig, muscle	0.01		Request		
Other terrestrial mammals, muscle	0.01		Request		
Cattle, fat	0.01		Request		
Pig, fat	0.01		Request		
Other terrestrial mammals, fat	0.01		Request		
Cattle, liver	0.01		Request		
Pig, liver	0.01		Request		
Other terrestrial mammals, liver	0.01		Request		
Cattle, kidney	○ 0.02		Request		
Pig, kidney	0.01		Request		
Other terrestrial mammals, kidney	○ 0.02		Request		
Cattle, edible offal	○ 0.02		Request		
Pig, edible offal	0.01		Request		
Other terrestrial mammals, edible offal	○ 0.02		Request		
Milk	0.01		Request		
Chicken, muscle	0.01		Request		
Other poultry, muscle	0.01		Request		
Chicken, fat	0.01		Request		
Other poultry, fat	0.01		Request		
Chicken, liver	0.01		Request		
Other poultry, liver	0.01		Request		
Chicken, kidney	0.01		Request		
Other poultry, kidney	0.01		Request		
Chicken, edible offal	0.01		Request		
Other poultry, edible offal	0.01		Request		
Chicken eggs	0.01		Request		
Other poultry, eggs	0.01		Request		
Fish	0.03	0.03			

The residue definition for agricultural products is sum of Tiadinil, metabolite D【4-methyl-1,2,3-thiazole-5-carboxylic acid】 and metabolite E【4-hydroxymethyl-1,2,3-thiazole-5-carboxylic acid】, expressed as Tiadinil. The definition for animal products is sum of Tiadinil and metabolite C【2-chloro-4-(4-methyl-1,2,3-thiazole-5-ycaboxylamino) benzoic acid】, expressed as Tiadinil. The residue definition for aquatic products is Tiadinil only.
The residue definition for agricultural and aquatic products will not be changed.

* The uniform limit 0.01 ppm will be applied to commodities not listed above.

* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

●：Commodities for which MRLs are to be lowered.

○：Commodities for which MRLs are to be raised. (*It should be noted that the residue definition (for agricultural / animal products) will be changed.)

§：Permitted for use in Japan.

Request：Request for setting/revising MRL was made by the MAFF.

Thiencarbazone-methyl

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Sugar beet	○ 0.04		Request		-

The residue definition is thiencarbazone-methyl only.

* The uniform limit 0.01 ppm will be applied to commodities not listed above.

○ : Commodities for which MRLs are to be raised.
Request : Request for setting/revising MRL was made by the MAFF.

Notes:

“Other cereal grains” refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat.

“Beans, dry” includes butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya and white beans.

“Other legumes/pulses” refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.

“Other potatoes” refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.

“Other cruciferous vegetables” refers to all cruciferous vegetables, except Japanese radish roots and leaves (including radish), turnip roots and leaves, horseradish, watercress, Chinese cabbage, cabbage, brussels sprouts, kale, *komatsuna* (Japanese mustard spinach), *kyona*, qing-geng-cai, cauliflower, broccoli, and herbs.

“Other composite vegetables” refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, *shungiku*, lettuce (including cos lettuce and leaf lettuce), and herbs.

“Other liliaceous vegetables” refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, *nira*, asparagus, multiplying onion, and herbs.

“Other umbelliferous vegetables” refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, *mitsuba*, spices, and herbs.

“Other solanaceous vegetables” refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper), and egg plant.

“Other cucurbitaceous vegetables” refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and *makuwauri* melon.

“Other mushrooms” refers to all mushrooms, except button mushroom, and *shiitake* mushroom.

“Other vegetables” refers to all vegetables, except potatoes, sugar beet, sugarcane, cruciferous vegetables, composite vegetables, liliaceous vegetables, umbelliferous vegetables, solanaceous vegetables, cucurbitaceous vegetables, spinach, bamboo shoots, okra, ginger, peas (with pods, immature), kidney beans (with pods, immature), green soybeans, mushrooms, spices, and herbs.

“Other citrus fruits” refers to all citrus fruits, except *unshu* orange (pulp), citrus *natsudaidai* (pulp), citrus *natsudaidai* (peel), citrus *natsudaidai* (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.

“Other berries” refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.

“Other fruits” refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.

“Other oil seeds” refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.

“Other nuts” refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.

“Other spices” refers to all spices, except horseradish, *wasabi* (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), *yuzu* (Chinese citron) peels and sesame seeds.

”Other spices (limited to roots and rhizome)” includes asafoetida roots, turmeric root, galangal rhizome and licorice root.

“Other herbs” refers to all herbs, except watercress, *nira*, parsley stems and leaves, celery stems and leaves.

“Edible offal” refers to all edible parts, except muscle, fat, liver, and kidney.

“Other terrestrial mammals” refers to all terrestrial mammals, except cattle and pig.

“Other poultry” refers to all poultry, except chicken.

“Other fish” refers to all fish, except salmoniformes, anguilliformes, and perciformes.

“Other aquatic animals” refers to all aquatic animal, except fish, shelled molluscs and crustaceans.

Item 2. Amendment of the Handling of Crossbred Progeny Specified in Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology

The government of Japan amended, on December 23 2020, Item VI "Handling of crossbred progeny" of the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, Minister's Secretariat, published on September 19, 2019) as below. (The full version is available at the MHLW website: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/bio/genomed/index_00012.html)

VI. Handling of crossbred progeny

For crossbred progeny obtained through a traditional breeding technique between a conventional breed etc.* and a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, the developer etc. concerned is not required to consult with the MHLW in advance and to notify the MHLW of the obtained product.

* A conventional breed etc. means: (i) a conventional breed, (ii) a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, or (iii) a breed made known to the public as a product evaluated to be safe as a food derived from recombinant DNA technology.

<Contact person>
Office of Health Policy on Newly Developed Food,
Food Safety Standards and Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

SUGIHARA Kaori (sugihara-kaoriaa@mhlw.go.jp)
Tel : 03-5253-1111 (ex 4283)　Fax: 03-3501- 4868

Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology

Published on September 19, 2019
Last amended on December 23, 2020

Decision by the Councillor for Environmental Health and Food Safety,
Minister's Secretariat

I. Definition

1. Genome editing technology

Genome editing technology is defined as a technology to modify a specific site of a specific base sequence on a chromosome using an enzyme recognizing the base sequence in order to provide specific functions. The technology that brings the final product that results in including foreign genes and their parts falls under recombinant DNA technology (the technology stipulated in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959; "Public Notice on the Specifications and Standards")).

2. Foods derived from genome editing technology

Foods derived from genome editing technology are foods that fall under any of the following items:

(1) An entire organism or its parts obtained by genome editing technology.

(2) A food including the entire organism or its parts obtained by genome editing technology.

(3) A food manufactured using microorganisms obtained by genome editing technology or a food containing such food.

3. Additives derived from genome editing technology

Additives derived from genome editing technology are defined as additives manufactured using organisms obtained by genome editing technology.

Moreover, additives derived from genome editing technology, when their final products are highly purified to be non-proteinous (such as amino acids) and meet both the following conditions (1) and (2), are handled as highly purified nonprotein additives (the additives decided by the Food Safety Commission of Japan (FSCJ) on April 28, 2005 as the additives stipulated in the standards for assessment*).

* Stance on Safety Assessments of Additives Produced Using Genetically Modified Microorganisms, Whose End Product Is Regarded as a Highly Purified Nonprotein Additive, Such as Amino Acids (supplementary provisions of Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms decided by the FSCJ on March 25, 2004)

(1) Purity of the product is high. For example, more than or equal to that of amino acids, nucleotides, vitamins, and monosaccharides, which are notified as designated additives.

(2) As compared with conventional additives, the contents of existing inactive ingredients in such additive do not significantly increase up to around the levels with safety concerns and such additive does not contain new inactive ingredients suggesting adverse effects.

II. Foods derived from genome editing technology for which notification is required

Notification described in section IV is required for any food derived from genome editing technology when the food satisfies either a or b, and also satisfies c below.

a. the food is an entire organism or its parts obtained by genome editing technology.

b. the food is an item manufactured using a microorganism obtained by genome editing technology.

c. the results brought from the technology show that the gene status of the organism or microorganism indicates no remaining foreign gene or its parts, and that deletion of bases, substitution and insertion of several bases, resulting insertion of one to several

mutations by cleavage etc. with an enzyme recognizing the specific base sequence occur.

When the gene status finally shows that foreign gene and its parts remain, the technology used for the item falls under recombinant DNA technology and such item is subject to safety assessment according to the Procedures for safety assessment of foods and additives derived from recombinant DNA technology (Public Notice of the Ministry of Health and Welfare No. 233 of 2000, "Public Notice on Procedures for Safety Assessment").

When the gene status of foods does not fall under the above conditions in section II, the necessity of notification or safety assessment is determined on a specific case-by-case basis by the Ministry of Health, Labour and Welfare (MHLW).

Foods manufactured and processed using notified foods derived from genome editing technology do not require notification.

III. Additives derived from genome editing technology for which notification is required

1. Additives derived from genome editing technology using microorganisms

Basically, it is assumed that additives comply with the compositional standards specified in the Public Notice on the Specifications and Standards.

Notification described in section IV is required for additives derived from genome editing technology when microorganisms used in manufacturing of such additives meet the following conditions:

- the gene status indicates no remaining foreign gene or its parts; and
- deletion of bases, substitution and insertion of several bases, resulting insertion of one to several mutations by cleavage etc. with an enzyme recognizing the specific base sequence occur.

However, notification is not required for items that fall under the following (1) or (2).

(1) Such additive is manufactured using a microorganism obtained by genome editing technology and it is clear that the gene constitution of the microorganism is equal to that of microorganisms belonging to the taxonomically identical species or naturally occurring microorganisms.

(2) Such additive is manufactured using a microorganism obtained by genome editing technology and is a highly purified nonprotein additive.

When the gene status finally shows that foreign gene and its parts remain, the technology used for the item falls under recombinant DNA technology and such item is subject to safety assessment according to the Public Notice on Procedures for Safety Assessment.

When the gene status of foods does not fall under the above conditions in section III, the necessity of notification or safety assessment is determined on a specific case-by-case basis by the MHLW.

2. Additives derived from genome editing technology using materials other than microorganisms

Follow the handling in section II.

IV. Procedure for notification, etc. (see Appendix)

1. As for foods derived from genome editing technology and additives derived from genome editing technology for which notification is required mentioned in the above sections II and III (hereinafter referred to as “foods etc. derived from genome editing technology”), the developer of such items, its representative, or a person/institute that can submit appropriate information (hereinafter referred to as “developer, etc.”) in order to confirm whether such foods, etc. fall under a target of notification or safety assessment, the developer, etc. request a prior consultation with the Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, the MHLW using Attachments 1-1 and 1-2 for foods and additives, respectively.

Foods, etc. derived from genome editing technology to be subject to a prior consultation are limited to those which have been developed for commercialization. For consultation, the information mentioned in section V, 1 or 2 is provided as much as possible.

2. The MHLW gives the developer, etc. the results about whether foods, etc. that have undergone a prior consultation fall under a target of notification or safety assessment using Attachment 2, as appropriate, confirming with Subcommittee on Genetically Modified Foods, Newly Developed Food Committee of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as "the Subcommittee").

   During the confirmation, when the Subcommittee determines to request for advice from the Food Safety Commission, Cabinet Office (hereinafter referred to as "the Food Safety Commission"), the Minister of Health, Labour and Welfare consults with the Food Safety Commission, and then based on the advice, determines how to proceed, and gives the results to the developer, etc.

3. For foods, etc. derived from genome editing technology, which have been confirmed to be subject to notification in a prior consultation, the developer, etc. notify the MHLW of the information mentioned in section V, 1 or 2 about the foods, etc. using Attachment 3 with necessary supporting data prior to marketing. The year and month of marketing are reported using Attachment 4 at a future date when such foods, etc. are marketed.

4. After receiving the notification of above 3, the MHLW posts and publishes the information mentioned in section V, 3 or 4 on the MHLW website promptly. The year and month of marketing are published after receiving a report of Attachment 4 by the developer, etc.

5. The same procedures are followed for imported products. Importers, etc. may perform the procedures instead of the developer, etc. when feasible.

6. Out of additives derived from genome editing technology subject to notification, those which are determined to fall under section III, 1, (1) or (2) by the developer, etc. are subject to a prior consultation with the reasons of determination and the materials as necessary. Items that fall under section III, 1, (1) or (2) based on the results of prior consultation are considered to have been notified by such prior consultation and do not require the procedures in the above sections 3 and 4.

V. Information to be notified and published

1. For foods derived from genome editing technology subject to notification, developer, etc. notify the MHLW of the following information.
   (1) Names of item and breed and summary (usage and intended use) of the developed food
   (2) Method of genome editing technology used and details of modification
   (3) Information on confirmation that there are no remaining foreign genes or their parts
   (4) Information on confirmation that confirmed changes in DNA do not cause production of new allergens having adverse effects on human health or increase of known toxic substances contained
   (5) For items in which modification affecting the metabolic system was performed in order to increase or decrease specific components, information on changes in major components (nutrient components only) related to the target metabolic system
   (6) Year and month of marketing (*Notify the MHLW of it after marketing)

2. For additives derived from genome editing technology, developer, etc. notify the MHLW of the following information.
   (1) Name of item and summary (usage and intended use) of the developed additive
   (2) Method of genome editing technology used and details of modification
   (3) Information on confirmation that there are no remaining foreign genes or their parts

(4) The fact that the additive complies with the compositional standards specified in the Public Notice on the Specifications and Standards

(5) Year and month of marketing (*Notify the MHLW of it after marketing)

3. For foods derived from genome editing technology, the MHLW publishes the following information.

(1) Names of notifier and developer, and date (year/month/day) of notification

(2) Names of item and breed and summary (usage and intended use)

(3) Summary of genome editing technology and gene modification used

(4) The fact that it is conformed that confirmed changes in DNA do not cause production of new allergens having adverse effects on human health or increase of known toxic substances contained

(5) Summary of changes in major components (nutrient components only) related to the target metabolic system

(6) Year and month of marketing (*Publish it after receipt of notification mentioned in 1, (6))

4. For additives derived from genome editing technology, the MHLW publishes the following information.

(1) Names of notifier and developer, and date (year/month/day) of notification

(2) Names of item

(3) Summary of genome editing technology and gene modification used

(4) The fact that the additive complies with the compositional standards specified in the Public Notice on the specifications and standards

(5) Year and month of marketing (*Publish it after receipt of notification mentioned in 2, (5))

VI. Handling of crossbred progeny

For crossbred progeny obtained through a traditional breeding technique between a conventional breed etc.* and a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, the developer etc. concerned is not required to consult with the MHLW in advance and to notify the MHLW of the obtained product.

* A conventional breed etc. means: (i) a conventional breed, (ii) a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, or (iii) a breed made known to the public as a product evaluated to be safe as a food derived from recombinant DNA technology.

VII. Others

The items specified in this procedures are reviewed, when necessary, based on usage record, future substantial scientific knowledge, or global trends, etc. for foods, etc. derived from genome editing technology.

It should be noted that when any fact not complying with this notice is found, the background, etc. are confirmed, conformity to the Food Sanitation Act and other acts are checked, and these results may be published with the information about such developer, etc.

This procedure comes into force on October 1, 2019.

Attachment 1-1: Prior Consultation Form: Food

Attachment 1-2: Prior Consultation Form: Additive

Attachment 2: Response Form

Attachment 3-1: Notification and Publication Form: Food

Attachment 3-2: Notification and Publication Form: Additive

Attachment 4: Notification Form for Marketing

Appendix: Flow diagram on the handling of foods derived from genome editing technology

Attachment 1-1: Prior Consultation Form: Food

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)
Name (For a corporation, its name and the representative's)

I/We hereby apply for prior consultation on the following food derived from genome editing technology according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

Name of item (the food)

(1) Names of item and breed, and the summary (usage and intended use) of the food

(2) Method of genome editing technology used and details of the modification

(3) Information on confirmation that there are no remaining foreign genes or their parts

(4) Confirmation that confirmed changes in DNA do not cause production of new allergens having adverse effects on human health or increase of known toxic substances contained

□ Confirmed □ Unconfirmed

(5) Whether modification performed in order to increase or decrease specific components affects the metabolic system.

□The modification affects the metabolic system.
□The modification does not affect the metabolic system.

(6) Year and month of marketing（If decided）

Notes:
- ✓ Information on above items (1) to (3) are mandatory.
- ✓ For above items (3) to (5), provide documents used for the confirmation.

Attachment 1-2: Prior Consultation Form: Additive

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)
Name (For a corporation, its name and the representative's)

I/We hereby apply for prior consultation on the following additive derived from genome editing technology according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

Name of item (the additive)

Attachment 1-2: Prior Consultation Form: Additive

(1) Name of item and summary (usage and intended use) of the additive

(2) Method of genome editing technology used and details of modification

(3) Information on confirmation that there are no remaining foreign genes or their parts

(4) Confirmation that the additive complies with the compositional standards specified in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959)

□ Confirmed □ Unconfirmed

(5) Year and month of marketing (If decided)

(6) Notification is not required for items that fall under either of the following conditions. Developer, etc. should provide information that explains the reason in prior consultation.

□ The additive is manufactured using a microorganism obtained by genome editing technology and it is clear that the gene constitution of the microorganism is equal to that of microorganisms belonging to the taxonomically identical species or naturally occurring microorganisms.

□ The additive is manufactured using a microorganism obtained by genome editing technology and is a highly purified nonprotein additive.

Notes:

- ✓ Information on above items (1) to (4) are mandatory.
- ✓ For above item (3), provide documents used for the confirmation.

Attachment 2: Response Form

Date/Year/Month

To:

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)

The MHLW responds as below on AA consulted by BB.

The food or additive derived from genome editing technology is subject to:

(1) the notification.
Please notify the food or additive according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

(2) the safety assessment.
The food or additive is categorized as a food or an additive derived from recombinant DNA technology, which requires safety assessment. Please consult with the MHLW about procedures to be carried out.

Attachment 3-1: Notification Form: Food

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)
Name (For a corporation, its name and the representative's)

I/We hereby notify the following food derived from genome editing technology before marketing according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

Name of item (the food)

Name of developer etc. (For a corporation, its name and the representative's)

Remarks

(1) Names of item and breed, and the summary (usage and intended use) of the food

(2) Method of genome editing technology used and details of the modification

(3) Confirmation that there are no remaining foreign genes or their parts

□ Confirmed □ Unconfirmed

(4) Confirmation that changes in DNA by genome editing technology do not cause production of new allergens having adverse effects on human health or increase of known toxic substances contained

□ Confirmed □ Unconfirmed

(5) Whether modification performed in order to increase or decrease specific components affects the metabolic system.

□The modification affects the metabolic system.
□The modification does not affect the metabolic system.

* If modification affecting the metabolic system was performed, information on changes in major components (nutrient components only) related to the target metabolic system

(1) Names of item and breed, and the summary (usage and intended use) of the food

(2) Method of genome editing technology used and summary of the modification

(3) Confirmation that changes in DNA by genome editing technology do not cause production of new allergens having adverse effects on human health or increase of known toxic substances contained

□ Confirmed □ Unconfirmed

(4) Whether modification performed in order to increase or decrease specific components affects the metabolic system.

□The modification affects the metabolic system.
□The modification does not affect the metabolic system.

* If modification affecting the metabolic system was performed, a summary on changes in major components (nutrient components only) related to the target metabolic system

Please note that this information will be published by the MHLW.

Attachment 3-2: Notification Form: Additive

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)
Name (For a corporation, its name and the representative's)

I/We hereby notify the following additive derived from genome editing technology before marketing according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

Name of item (the additive)

Name of developer etc. (For a corporation, its name and the representative's)

Remarks

(1) Names of item and breed, and the summary (usage and intended use) of the additive

(2) Method of genome editing technology used and details of the modification

(3) Confirmation that there are no remaining foreign genes or their parts

□ Confirmed □ Unconfirmed

(4) The fact that the additive complies with the compositional standards specified in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959)

□ Confirmed □ Unconfirmed

Attachment 3-2: Publication Form: Additive

(1) Name of item (the additive)

(2) Method of genome editing technology used and summary of the modification

(3) The fact that the additive complies with the compositional standards specified in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959)

□ Confirmed □ Unconfirmed

Please note that this information will be published by the MHLW.

Attachment 4: Notification Form for Marketing

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)
Name (For a corporation, its name and the representative's)

I/We hereby notify the start of selling of the following food or additive derived from genome editing technology according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

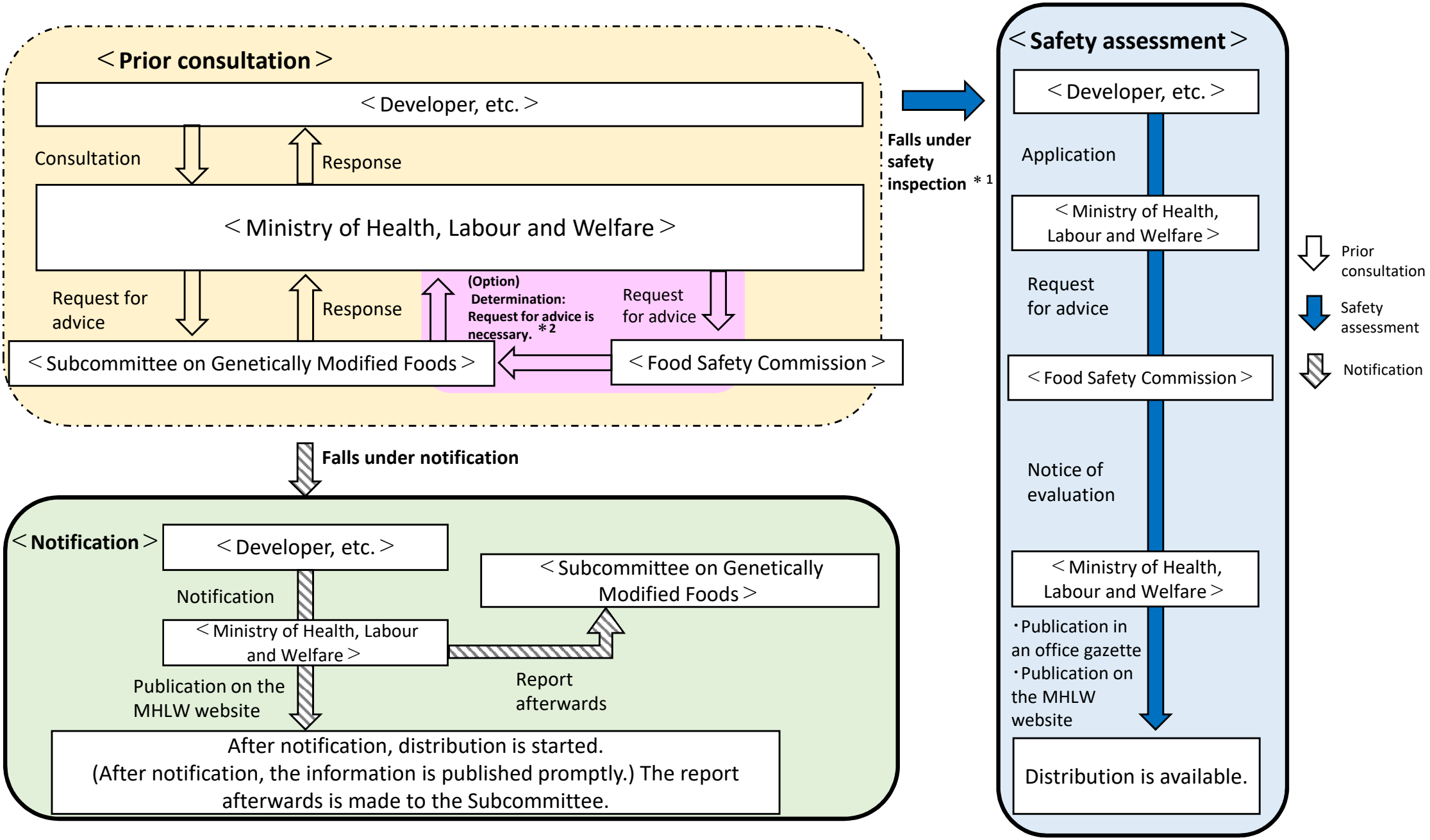
Name of item (the food or the additive)

Name of developer etc. (For a corporation, its name and the representative's)

Year and month of marketing

Flow diagram of handling of foods derived from genome editing technology

Appendix



*1 As foods derived from recombinant DNA technology, for foods, etc. which are determined to “fall under safety assessment,” Ministry of Health and Welfare Notification No. 233 of 2000 is applied mutatis mutandis.

*2 For new foods and new technology, advice is requested for the Food Safety Commission as necessary and their handling, etc. are determined by the Subcommittee on Genetically Modified Foods